

REMARKS

Reconsideration and withdrawal of the restriction requirement and species election is respectfully requested in view of the remarks herein.

The August 21, 2007 Office Action required restriction from among the following Groups:

Group I: Claims 1-14, drawn to a method of immunizing an equine host, classified in class 424, subclass 184.1; and,

Group II: Claims 15-29, drawn to a vaccine composition, classified in class 435, subclass 235.1.

Applicants hereby elect, with traverse, the claims of Group II.

Furthermore, an election of species was also required:

- One recombinant virus must be elected: canary pox, fowlpox or pigeon pox
 - if canary pox is elected, a single strain must be elected for the expression of influenza HA protein (see claims 13 and 14)
- One adjuvant must be elected
 - if the polymer adjuvant having monomeric units is elected, further election is required as follows:
 - R1 and R2 are either identical or different
 - H or CH3 for each of R1 and R2
 - X is 0 or 1, and
 - Y is 1 or 2
 - if acrylic polymer is elected, further election between allyl sucrose or allyl pentaerythritol is required.

Applicants hereby elect, with traverse, the species canarypox virus and the strain HA influenza A/equi-2/Newmarket/2/93, and poly(ethylene-co-maleic acid anhydride), e.g., EMA, poly(ethylene-co-2,5-furandione), such that R1 and R2 are identical, R1=H, R2=H, X=0 and Y=2.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs

the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” Id.

The Office Action states that the Groups of claims are distinct as the claims of the defined Groups are related as product and process of use where the product or process can be practiced with another materially different product or in a materially different process of using that product. Specifically, the Office Action alleges that "a recombinant virus can be used in materially different methods such as to screen compounds or express proteins." Office Action at 2.

Applicants respectfully assert that all of the claims are interrelated, and that the search and examination of the claims will be co-extensive. For example, the claims of Group II as elected with traverse herein are directed to the vaccine composition itself, which composition is used in the method of immunization as claimed in claim 1. Therefore, the search and examination of the claims of Group II, i.e., a search for the vaccine composition itself, will necessarily include a search for the use of the vaccine composition. Accordingly, the search and examination of both of the Groups of claims will be co-extensive and overlapping.

Furthermore, for a restriction requirement to be proper, it must satisfy both of the above elements. Accordingly, the present restriction requirement is improper and must be withdrawn because the Office Action only alleges that the inventions are distinct, as described above. The Office Action provides no showing that search and examination of the claims would be an undue and serious burden, nor does the Office Action show that at the very least, the search and examination of the claims of Groups I and II would be an undue and serious burden. Therefore, the restriction requirement is improper because it does not satisfy both requirements for restriction and should be withdrawn.

The Office Action additionally required the election of a recombinant virus and specific strain, and a specific adjuvant.

The Examiner is respectfully reminded that M.P.E.P. § 808.01(a), states that “where there is no disclosure of relationship between species (see M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the

species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

It is respectfully submitted that there is a disclosed relationship between the species as the members of the first species are all pox viruses suitable for use in the present invention, and the members of the second species are all adjuvants suitable for use in the present invention. Applicants respectfully request that at the very least, the species election be rewritten to allow the search and examination of a second pox virus or a small number of adjuvants.

In view of the remarks herein, enforcing the present restriction requirement and elections of species would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the lack of assertions in the Office Action as to the requisite showing of serious burden, in contrast to the requirements of MPEP 803.04. Indeed, the search and examination of each Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. Furthermore, the requirement of election of a single pox virus (including a particular strain) and adjuvant is unduly burdensome on the Applicant, especially in view of the lack of burden placed on the Examiner. All of the preceding, therefore, mitigate against restriction and election species.

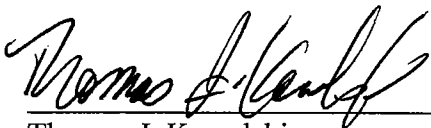
In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the restriction requirement and election of species, and a second pox virus or a small number of adjuvants is searched and examined together.

CONCLUSION

Reconsideration and withdrawal of the restriction requirement and election of species and an early and favorable examination on the merits is respectfully requested in view of the remarks herein.

Respectfully submitted,

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